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(71) Applicant *(for all designated States except US)*: **BIOJECT INC.** [US/US]; 20245 SW 95th Avenue, Tualatin, Oregon 97062 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **LANDAU, Sergio** [US/US]; 49 South Peak, Laguna Niguel, California 92677 (US).

(74) Agent: **HEUSER, Peter, E.**; Kolisch Hartwell, PC, 200 Pacific Building, 520 SW Yamhill St., Portland, Oregon 97204 (US).

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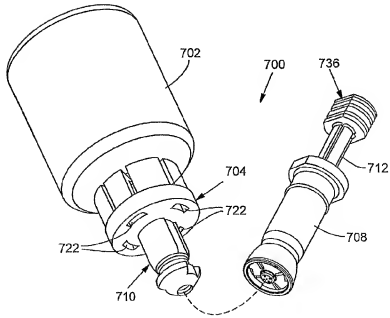

(57) Abstract: The disclosure provides a filling cap for use in a needle-free injection system. The filling cap includes a vial-engagement portion and an ampule-engagement portion with a frangible portion extending therebetween. The vial-engagement portion is designed to removably engage a vial of to be transferred into an ampule, and the ampule-engagement portion is designed to nonremovably engage an ampule.

WO 2006/088513 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

NEEDLE-FREE INJECTION DEVICE

This application claims the benefit of and is a continuation of U.S. Patent Application Serial No. 11/152,688 filed June 13, 2005, which is a continuation-in-part of U.S. Patent Application Serial No. 11/069,538 filed February 28, 2005, which claims the benefit of U.S. Provisional Patent Application No. 60/653,352 filed February 15, 2005 entitled Needle-Free Injection Device for Individual Users. For the purposes of priority claiming in the United States, this application further claims the benefit of and is a continuation-in-part of U.S. Patent Application Serial No. 10/976,342 filed October 26, 2004, which is a continuation-in-part of U.S. Patent Application Serial No. 10/861,891 filed June 4, 2004, which is a continuation-in-part of U.S. Patent Application Serial No. 10/805,109 filed March 19, 2004. This application incorporates each of the above-mentioned applications by reference in their entirety for all purposes.

Background

Needle-free injection systems provide an alternative to standard fluid delivery systems, which typically uses a needle adapted to penetrate the outer surface of an injection site. Typically, needle-free injection systems are designed to eject the fluid from a fluid chamber with sufficient pressure to allow the fluid to penetrate the target to the desired degree. For example, common applications for needle-free injection systems include delivering intradermal, subcutaneous and intramuscular injections into or through a recipient's skin. For each of these applications, the fluid must be ejected from the system with

sufficient pressure to allow the fluid to penetrate the tough exterior dermal layers of the recipient's skin.

When using the same device to deliver inoculations, immunizations or the like, to different individuals, preventing cross-contamination between injection recipients and prevention of contamination of the filling source must be a priority. Thus, it is desirable to provide a device that allows a user to move with reasonable speed from one injection recipient to another while maintaining adequate protections against cross-contamination. In addition, it will often be desirable to obtain the above advantages while also keeping waste to a minimum (e.g., by avoiding unnecessary disposal of portions of the injection system).

It is also desirable in many applications that an injector be relatively small, hand-held, and ergonomically comfortable so that it can be easily handled by the health care provider. When a spring loaded injector is being used, it is also desirable that the injector spring be easily compressed. These and other advantages of the preferred embodiments will be apparent as this description continues.

Summary

The disclosure provides a filling cap for use in a needle-free injection system. The filling cap includes a vial-engagement portion and a needle-free syringe-engagement portion with a frangible portion extending therebetween. The vial-engagement portion is designed to removably engage a vial of fluid to be transferred into a needle-free syringe, and the needle-free syringe-

engagement portion is designed to nonremovably engage a needle-free syringe.

Another aspect of the disclosure provides a method for filling a needle-free injector with injection fluid. The method includes the following steps, but not necessarily in the order recited: selecting a needle-free syringe having an injection orifice at one end; selecting a vial with injection fluid therein; mounting one end of a vial adapter to the vial such that a second end of the vial adapter faces away from the vial; selecting a filling cap with one end complementing the configuration of the one end of the needle-free syringe and the other end complementing the configuration of the second end of the vial adapter, and having a frangible portion disposed between the two ends; nonremovably fixing the one end of the filling cap to the one end of the needle-free syringe; mounting the other end of the filling cap to the second end of the vial adapter; transferring injection fluid from the vial to the needle-free syringe; and breaking the frangible portion of the filling cap without removing the one end from the needle-free syringe.

A third aspect of the disclosure provides a needle-free syringe for use in a needle-free injection system. The needle-free syringe includes a needle-free syringe body that is open on one end and an injection orifice at a second end. A plunger is disposed in the open end of the needle-free syringe body for drawing injection fluid into and forcing injection fluid out of the needle-free syringe body via the injection orifice. A filling cap is frangibly mounted to the second end of the needle-free syringe body. The filling cap has an outwardly-

extending recess for receiving an outwardly extending portion of a vial adapter mounted to an injection-fluid-containing vial.

Another aspect of the disclosure is a needle-free injection system. The system includes an injector body and a trigger system disposed on the body for firing the injector. Also included is a needle-free syringe to be positioned within the body. The needle-free syringe includes an open end having a plunger positioned for drawing injection fluid into and driving injection fluid out of the needle-free syringe. The needle-free syringe has a second end with an injection orifice. A system for providing power to drive the plunger forward to drive injection fluid out of the injection orifice is also provided, as is a filling system with a filling cap having one end that is frangibly mounted adjacent the second end of the needle-free syringe, radially outwardly of the injection orifice. The filling cap typically has another end defining a vial adapter mount for removably mounting the filling cap to a vial adapter that is positioned on a vial having injection fluid therein.

Brief Description of the Drawings

Fig. 1 is a perspective view of a first embodiment of the present invention after the cartridge has been inserted in the injector but before the cartridge is locked in position.

Fig. 2 is a perspective view corresponding to Fig. 1 except that the cartridge has been locked into position.

Fig. 3 is a perspective view corresponding to Fig. 1 except that the trigger sleeve has not yet been slid forwardly as the injector is pressed against the patient.

Fig. 4 is an end view of the first embodiment.

Fig. 5 is an exploded view of the first embodiment.

Fig. 5A is an enlarged perspective view of the ratchet rings of the first embodiment.

Fig. 6 is a side elevation sectional view of the first embodiment before compression of the main spring begins.

Fig. 6A is a fragmentary side elevation sectional view of the first embodiment after the main spring has been loaded.

Fig. 6B is a fragmentary side elevation sectional view of the first embodiment after the main spring has been loaded, and after the trigger sleeve has slid forward to fire but in the instant before firing takes place.

Fig. 6C is a fragmentary side elevation view of the first embodiment after the injector has been fired (corresponding to Fig. 6).

Fig. 7 is a side elevation sectional view of the first embodiment after the main spring has been compressed but before the nozzle has been filled with injection fluid.

Fig. 8A is a side elevation sectional view of the first embodiment after the main spring has been compressed and after the nozzle has been filled with injection fluid.

Fig. 8B is a side elevation sectional view corresponding to Fig. 8A except that section is 90° offset.

Fig. 9 is a side elevation sectional view of a second embodiment before compression of the main spring.

Fig. 10A is a side elevation sectional view of the second embodiment after compression of the main spring and after the nozzle has been filed with injection fluid.

Fig. 10B is a side elevation sectional view corresponding to Fig. 10B except that the section is 90° offset.

Fig. 11 is a side elevation sectional view of the second embodiment after compression of the main spring but before the nozzle has been filled with injection fluid.

Fig. 12 is a side elevation sectional view of the winder portion at the proximal end of the first embodiment.

Fig. 13 is a fragmentary side elevation sectional view of a third embodiment.

Fig. 14 is a fragmentary perspective view of the plunger with ram portion of the third embodiment showing the frangible member broken to prevent re-use.

Fig. 15 is a fragmentary perspective view of the plunger/ram portion of the third embodiment, prior to the point at which the frangible member is broken.

Fig. 16 is a fragmentary perspective view of the plunger and the ram of the third embodiment showing that when the plunger is withdrawn after the frangible member is broken, the plunger does not follow.

Fig. 17 is a perspective view of the plunger of the third embodiment showing the frangible member intact.

Fig. 18 is an exploded isometric view showing alternate embodiments of a vial adapter and nozzle/filling assembly according to the present description.

Fig. 19 is a sectional view depicting operative engagement of the vial adapter and nozzle/filling assembly of Fig. 18, so as to enable a dose of injectable fluid from an external supply (e.g., a vial) to be loaded into the injection device.

Fig. 20 depicts a non-compliant attempt to fill the nozzle/filling assembly of Figs. 18 and 19 after detachment of the filling adapter.

Fig. 21 is a partial sectional view depicting a further alternate embodiment of a vial adapter and nozzle/filling assembly according to the present description.

Fig. 22 is an exploded isometric view showing another alternate embodiment of a vial adapter according to the present description.

Fig. 23 depicts the vial adapter of Fig. 22 operatively engaged with an alternate nozzle/filling assembly according to the present description.

Fig. 24 is an exploded view of yet another embodiment to be used with a prefilled cartridge.

Fig. 25 is a side elevation sectional view of the embodiment of Fig. 24 after a new, prefilled cartridge has been mounted in place.

Fig. 26 is a side elevation sectional view of the embodiment of Fig. 24 after the injector has been fired.

Fig. 27 has a side elevation sectional view of the embodiment of Fig. 24 after the ram extension has been withdrawn and the cartridge is ready to be removed and replaced.

Fig. 28 is an exploded isometric view of a filling system according to the present description.

Fig. 29 A-E are side elevation sectional views of the filling system of Fig. 28; Fig. 29A depicts an initial position with the vial adapter in place on the vial; Fig. 29B corresponds to Fig. 29A except that the filling cap is in position on the vial adapter; Fig. 29C corresponds to Fig. 29B except that the plunger is now shown in its withdrawn position; Fig. 29D shows the filling cap being broken away from the needle-free syringe at the frangible portion; and Fig. 29E shows the needle-free syringe after the filling cap, vial adapter and vial have been broken away.

Fig. 30 is an isometric view of the filling system of Fig. 28, with the filling cap, vial adapter and vial broken away from the needle-free syringe.

Fig. 31 is an enlarged, fragmentary side elevation sectional view of the filling cap of the embodiment of Fig. 28 as it is being broken away from the needle-free syringe.

Fig. 32 is an enlarged, fragmentary isometric view of the needle-free syringe of Fig. 28 after the filling cap has been broken away.

Fig. 33 is an isometric view of a needle-free syringe and intradermal spacer of an intradermal injection system, with the needle-free syringe and intradermal spacer not yet mounted to one another.

Fig. 34 is an isometric view of a needle-free syringe and intradermal spacer of the intradermal injection system of Fig. 33 with the needle-free syringe and intradermal spacer mounted to one another.

Fig. 35 is an enlarged side elevation sectional view of the needle-free syringe and intradermal spacer mounted to one another as in Fig. 34.

Detailed Description of the Preferred Embodiments

Figs. 1-35 depict various embodiments of a spring-loaded needle-free injection device. As will be explained in more detail below, the device typically is implemented as a single-use injection system including a fluid cartridge that may be engaged with an injector mechanism such as that depicted in the figures. A fluid chamber within a nozzle/cartridge may be filled with a dose of injectable fluid. Typically, filling is accomplished from an external supply of fluid, which may include a vial adaptor that allows the external supply to be selectively coupled to the nozzle-cartridge filling assembly. After filling, the external supply of fluid is decoupled from the nozzle/cartridge filling assembly by simply removing the external supply and vial adaptor from engagement with the nozzle/cartridge assembly.

Embodiment of Figs. 1-8 and 12

Before describing the operation of the depicted system, the various parts and their relationship to one another will first be described. A first embodiment of the injector system is depicted at 10 in Figs.1-8 and 12. For an identification and description of the various parts, reference should first be made to Figs. 5 and 6-8. The basic components of injector 10 are a main body 12 (see Fig. 5), a trigger sleeve 14, a winder 16, a cartridge 20 and a

cartridge lock 22. Trigger sleeve 14 is designed to slideably fit over main body 12. Winder 16 is rotatably mounted to trigger sleeve 14 such that a spring may be compressed to provide power for the injection. Winder 16 is located at a proximal end of injector 10, which is opposite the end to which cartridge 20 is mounted.

Beginning at the proximal end of injector 10, a dosage knob 24 is included. Dosage knob 24 includes fine, left-handed threads 26 which engage complementing fine threads 28 in a dosage drum 30. A dosage spring 32 is positioned within dosage knob 24 and dosage drum 30 and extends between the proximal end of the dosage knob and a dosage spring seat 34. Positioned within dosage spring 32 is a slide bushing extension 36 and a slide bushing extension seat 38. Slide bushing extension 36 and slide bushing seat 38 mount to and extend the length of a slide bushing 88, which will be described in more detail below.

Positioned around dosage spring 32 within the proximal end of injector 10 is an enlarged ratchet spring 40 which is designed to bias a second ratchet ring 42 toward a first ratchet ring 44. The first and second ratchet rings each include a plurality of teeth 45 and 43, respectively (see Fig. 5A), that are designed to permit relative rotation in one direction but not another. The teeth can be seen to be tilted to one side or sloped to facilitate this sliding in one direction and engagement in the other direction. Therefore, when winder 16 causes second ratchet ring 42 to rotate in a clockwise direction, the spring bias provided by ratchet ring 40 causes teeth 45 and 43 to engage and thereby rotate first ratchet ring 44 in that first direction. However, when

winder 16 is rotated in a counterclockwise direction, teeth 45 and 43 of first and second ratchet rings 44 and 42 are permitted to slide over one another

A pair of small winder pins 46 are positioned within second ratchet ring slots 47 and winder slots 48 so that when the two ratchet rings are positioned within winder 16, relative rotation is not permitted between the second ratchet ring and the winder.

As seen best in Figs. 5 and 12, a pair of long pins 50, each having a head at its proximal end, are positioned within notches 52 in the outer diameter of first ratchet ring 44, and extend through a pair of diametrically opposed holes 54 in dosage drum 30. Long pins 50 extend in a distal direction past dosage spring seat 34, nut 56, washer 58, and engage notches 68 in the outer diameter of a torque nut 60. A pair of dosage screw pins 64 extend between notches 66 in the inner diameter of torque nut 60 and a dosage screw 62. Thus, dosage screw pins 64 prevent relative rotation between torque nut 60 and dosage screw 62. Because long pins 50 prevent relative rotation between first ratchet ring 44, dosage drum 30 and torque nut 60, relative rotation is not permitted between first ratchet ring 44 and dosage screw 62, for reasons that will become apparent as this description continues.

A pair of so-called clam shell halves 70 are mounted between dosage drum 30 and trigger sleeve 14 to prevent axial displacement between these two components, but permit relative rotation therebetween. Clam shell halves 70 are held together by a pair of clam shell screws 72. Clam shell halves 70 are engaged with trigger sleeve 14 by a pair of clam shell pins 74. The only engagement between clam shell halves 70 and dosage drum 30 is the

engagement of a proximal leg 71 of the substantially U-shaped clam shell halves. That is, proximal leg 71 engages a complementing slot 73 in dosage drum 30. Thus, again, the dosage drum, winder and associated parts are held in engagement with the trigger sleeve, but relative rotation is permitted between them so that the winder can be rotated to compress a main spring 102, as will be understood as this description continues.

Continuing in a distal direction, a pair of trigger locks 76 are pivotally mounted to trigger sleeve 14 by trigger lock pivot points 78. Trigger locks 76 each include radially-extending trigger lock legs 80 that engage a ledge or notch 82 in main body 12. Each of the trigger locks 76 includes a trigger lock spring 84 that pushes the distal end of the trigger locks outwardly, thereby causing trigger lock legs 80 to engage notch 82 until the trigger locks are depressed against the outward bias of the trigger lock springs. In most applications only a single trigger lock will be included even though two such trigger locks are included in the depicted embodiment.

A trigger sleeve window 86 is provided in the side of trigger sleeve 14 so that a visual indicator can be provided to ensure the proper positioning of the components prior to firing. Window 86 can also be used to provide a read-out of the dosage that is being injected.

Referring again to the exploded view of Fig. 5 and the assembled view of Figs. 6-8, slide bushing 88 can be seen to extend through trigger sleeve 14 and within winder 16 to contact the distal end of slide bushing extension 36. In some embodiments there may be a single slide bushing rather than the two-part slide bushing/slide bushing extension shown in injector 10.

A trigger spring 90 can be seen to the positioned within slide bushing 88. Trigger spring 90 is seated in a trigger spring seat 92 which in turn is positioned within a firing sleeve 94. Four hardened steel balls 96 are initially positioned within four ball seats 98 in firing sleeve 94 for purposes that will become apparent as this description continues.

An upper spring seat 100 provides a proximal seat for main spring 102, which provides injection power for injector 10. A main spring seat 104 provides a distal seat for main spring 102. A substantially square washer 106 is shown to be positioned between main spring seat 104 and a ram 108. As shown, main spring seat 104 includes a central opening through which ram 108 extends. A ram bolt 110 extends out of the proximal end of ram 108 to provide a hardened surface for the proximal end of ram 108. Ram 108 includes a ram seat 112 and, at its distal end, a head 114 which is defined by a notch in the ram. The configuration of head 114 is designed to facilitate engagement of cartridge 20.

At the distal end of injector 10 is a cartridge lock 22, which is mounted to main body 12 by a cartridge holder 118. Specifically, external threads 120 in cartridge holder 118 engage with complementing internal threads 122 in main body 12 in order to properly engage the cartridge holder to the main body. A detent pin 128 and a small spring are provided to cause cartridge lock 22 to click into its locked position.

Cartridge 20 can be seen to include a plunger 130 positioned within a chamber 132 in a nozzle 140. The distal end of nozzle 140 includes an injection orifice 142. Plunger 130 includes a substantially U-shaped proximal

end 136, which is designed to engage head 114 in the distal end of ram 108. This provides a solid mount that will convey forces conveyed between the ram and the plunger and yet permits easy engagement and disengagement.

Cartridge lock 22 includes a cartridge lock opening 138 (Figs. 1-4) so that the cartridge can be moved into position from one side and the U-shaped proximal end 136 of plunger 130 may be engaged with head 114 in ram 108. A cartridge holder opening 137 is also provided so that in the cartridge insertion condition, cartridge lock opening 138 is in alignment with the cartridge holder opening. As shown in Figs. 1 and 2, cartridge lock 22 is then rotated 90° with respect to the rest of injector 10 so that cartridge lock opening 138 and cartridge holder opening 137 are no longer in alignment. This effectively locks cartridge 20 in place in injector 10 for firing.

Nozzle 140 may be loaded with injection fluid by the system described in my application Serial No. 10/976,342, or any conventional system. Once nozzle 140 is loaded, the nozzle and its injection orifice 142 may be placed against the patient for injection.

While the depicted embodiment is a spring-loaded embodiment, it should be understood that it is also possible to use a gas-powered injector (not shown) in connection with the depicted described system for loading a cartridge from the side. Gas-powered systems are included in U.S. Patent Nos. 6,096,002, 6,607,510, 6,645,170, and 6,689,093, which are incorporated herein by reference.

Fig. 6 depicts injector 10 in its initial position prior to filling of the nozzle 140 and prior to the point at which main spring 102 is loaded. This is also

shown in Fig. 6C. In this position it can be seen that both dosage spring 32 and main spring 102 are in their relaxed positions. Legs 80 of trigger locks 76 are in engagement with notch 82 in main body 12. If the patient now wishes to perform an injection, the patient holds trigger sleeve 14 with one hand, normally the left, and turns winder 16 in a clockwise direction. The ratchet mechanism eases the winding process because winder 16 can merely be turned repeatedly one direction and then the other rather than having to rotate the winder entirely around. In certain applications this may be an easier operation than the complete rotation, particularly for clients who may have decreased motor skills.

As winder 16 is rotated in the clockwise direction, the winder carries second ratchet ring 42. Ratchet spring 40 holds teeth 43 of second ratchet ring 42 against teeth 45 of first ratchet ring 44. This causes first ratchet ring 44 to rotate and along with it so rotates dosage drum 30, torque nut 60 and dosage screw 62. When winder 16 is ratcheted back in a counter clockwise direction, the teeth 45 and 43 of first and second ratchet rings 44 and 42, respectively, slip across each other without causing a reverse rotation of first ratchet ring 44, the dosage drum 30, torque nut 60 or dosage screw 62. As a result of this repeated back and forth rotation of winder 16, dosage screw 62 is turned down into the injector, exerting a forward or downward force on main spring seat 104 and main spring 102 positioned therebelow. This compresses main spring 102 for the injection operation. As the compression of main spring 102 is completed, trigger spring seat 92, firing sleeve 94 and balls 96 move from the position shown in Fig. 6 and 6C to the position shown in Figs.

7 and 6A where the balls are positioned immediately below the head of ram bolt 110.

At this point, injector 10 is ready to be loaded with medication, vaccine or other medicinal fluid. In order to retract the plunger and thereby draw fluid from a vial, injector 10 is held in an upright position with the vial at the top. Dosage knob 24 is then rotated in a counter clockwise direction, thereby drawing back slide bushing extension 36, slide bushing extension seat 38, slide bushing 88, firing sleeve 94, ram 108 and plunger 130. This draws fluid into chamber 132, thus preparing injector 10 for injection. This so-called ratchet-ready position is depicted in Figs. 8A and 8B.

Injector 10 cannot be fired until trigger locks 76 are both depressed, or in the event only one trigger lock is included, the injector cannot be fired until that single trigger lock is depressed. This provides a safety in order to prevent inadvertent firing. To fire injector 10 and inject fluid into the patient, trigger locks 76 are depressed, thereby releasing the engagement between trigger lock legs 80 and notch 82 in main body 12. This is done after orifice 142 of nozzle 140 is pressed against the skin of the patient receiving the injection. Thus, with the trigger locks depressed, injector 10 is pressed against the patient, causing trigger sleeve 14 to slide in a forward direction toward the patient to the position shown in Fig. 7. This causes balls 96 to shift outwardly to the position shown in Fig. 6B. This Fig. 6B shows a disposition of parts that will be only momentary, that is, immediately after balls 96 clear the head of ram bolt 110. Ram 108 will quickly shoot forward, causing

plunger 130 to drive fluid in chamber 132 out of orifice 142 and through the skin of the patient.

After the injection process is completed, trigger sleeve 14 is slid back to its original position by spring 32 so that trigger lock legs 80 engage notch 82 of main body, and cartridge lock 22 is rotated to permit sideways removal of nozzle 140. When injector 10 is to be reused, another nozzle is loaded in place and the process is repeated.

Embodiment of Figs. 9-11

The injector of Figs. 9-11 is identical to the injector of Figs. 1-8 except that the ratchet mechanism associated with winder 16 has been deleted. Therefore, it is necessary to rotate the winder repeatedly around with respect to trigger sleeve 14 in order to cause main spring 102 to be compressed for firing. It can be seen that the first and second ratchet rings and other associated parts have been deleted from this embodiment 210. Because the other features are typically identical to those described in connection with injector 10, the description of the construction and operation of those other parts will not be repeated. The numbering of the parts has been maintained the same as the embodiment of Figs. 1-8 and 12 because those parts are typically identical in this second embodiment.

Embodiment of Figs. 13-17

Figs. 13-17 show a slightly different version of the nozzle and ram assemblies. As noted above, it is desirable that once a cartridge or nozzle has been used, that it be disabled so that it cannot be reused. This is desirable to prevent cross-contamination between patients. In order to

provide that capability in the disclosed injector 10, the nozzle and ram assemblies may be modified as shown in Figs. 13-17.

Numbers corresponding to Figs. 1-8 and 12 are shown, except for similar parts, 100 has been added. Therefore, the nozzle has been identified at 240, the plunger at 230, the nozzle U-shaped proximal end at 236, and the ram at 208. A frangible member 216, shown best in Fig.17, is mounted to U-shaped proximal end 236 by frangible or breakable tabs 217 for purposes that will become apparent as this description continues.

Instead of notched head 114 in ram 108 of injector 10, the embodiment of Figs. 1-8 includes two flanges in addition to the flange that forms ram seat 212. As shown, a small distal flange is indicated at 214, and a middle flange is shown at 213. As shown best in Fig.13, middle flange 213 is disposed proximally of distal flange 214 and includes a shoulder 215 on its distal side.

In operation, nozzle 240 is filled in the same manner as described above with respect to nozzle 140. Ram 208 is drawn back so that distal flange 214 contacts frangible member 216. Because the loading force is so small, perhaps as low as ten pounds or even five pounds or less, frangible member 216 will not break as plunger 230 is pulled back to draw injection fluid into chamber 232.

When the injection force is applied via ram 208, shoulder 215 of middle flange 213 drives through frangible member 216 before distal flange 214 contacts U-shaped proximal end 236 of plunger 230. Shoulder 215 and middle flange 213 close off enough of U-shaped proximal end 236 to prevent

fragments of frangible member 216 and tabs 217 from falling out and potentially causing jamming of the various components.

After firing, nozzle 240 is removed from the injector as in the previously-described embodiments. A new nozzle, with an intact frangible member 216, is installed for the next injection. This prevents cross-contamination between patients. If, rather than replacing nozzle 240, the user attempts to reuse and reload the nozzle, the absence of frangible member 216 will cause distal flange 214 to merely pull out of U-shaped proximal end 236 as shown in Fig. 16. This will prevent plunger 230 from being drawn back in chamber 232, and a fluid-loading suction will not be created. Thus, this embodiment of the present invention provides a simple yet effective way to prevent cross-contamination and is a reason this is a preferred embodiment.

As with the first embodiment discussed above, it should be understood that it is possible to use this embodiment of Figs. 13-17 with a gas-powered injector such as those systems described in U.S. Patent Nos. 6,096,002, 6,607,510, 6,645,170, and 6,689,093, which are incorporated hereby reference.

Embodiment of Figs. 18-20

Another manner in which cross-contamination can be prevented is to use one of the loading vial adaptor systems described in the parent application. To avoid confusion, the numbering has been retained from the parent application. Figs. 18-20 depict an embodiment of a nozzle/filling assembly 280 and vial adapter 282. Vial adapter 282 typically includes a main body 284, an inner valve sleeve 286 and a plug 288. Vial adapter 282

typically is attached to and carried on a multiple-dose container (e.g., vial 290) of injectable fluid. Nozzle/filling assembly 280 may include a nozzle 292, a filling adapter 294 secured to the front end of the nozzle, and a piston 296 slidably disposed within a fluid chamber 298 of the nozzle.

Nozzle/filling assembly 280 typically is provided to the end user in a ready-to-fill state. In this state, the nozzle/filling assembly may be operatively engaged with vial adapter 282 to perform the filling operation, in which a dose of injectable fluid is drawn from vial 290 through injection orifice 300 and into fluid chamber 298 of nozzle 292. To allow the injection to go forward, filling adapter 294 is broken away from nozzle 292. Filling adapter 294 is specially configured to operatively engage with vial adapter 282 to perform the filling operation. Typically, the system is configured so that filling cannot occur after filling adapter 294 is broken away. Thus, a single simple step permits the injection to go forward, while simultaneously disabling the ability to refill nozzle 292.

Main body 284 of vial adapter 282 includes a vial gripping section 310 (see Fig. 19) adapted to grip a vial of injectable fluid (e.g., vial 290), and several fingers extending axially away from the gripping section. The extending structures may include relatively rigid fingers 320 and relatively flexible fingers 322 (see Fig. 18). In the depicted embodiment, there are four rigid fingers, with a flexible finger disposed between each rigid finger, for a total of eight fingers, though it should be appreciated that different numbers of fingers may be employed in various configurations.

Vial adapter 282 includes a piercing member or spike 321 configured to pierce a sealed opening of vial 290. Openings are provided on piercing member 321 to enable injectable liquid from vial 290 to flow into a central channel 326 defined within a cylindrical member 328 extending away from gripping section 310 between fingers 320 and 322. Plug 288 is fitted snugly into the distal end of cylindrical member 328. As indicated in Figs. 18 and 19, plug 288 includes channels 330 configured to permit fluid to be drawn out of central channel 326 and into the area around injection orifice 300 of nozzle 292. As will be explained in more detail, inner valve sleeve 286 may be axially movable between a position in which it seals off channels 330, and an unsealed position, in which liquid is permitted to pass out through the channels to injection orifice 300.

Referring specifically to Fig. 19, to fill the device, nozzle/filling assembly 280 is first inserted into and received within vial adapter 282. Prior to this, nozzle/filling assembly 280 may first be secured within an injector device or other mechanism. As nozzle/filling assembly 280 is inserted into vial adapter 282, a ramped portion 340 on the outer diameter of filling adapter 294 bears against flexible fingers 322, urging them outward. Flexible fingers 322 are urged far enough outward by filling adapter 294 so that the flexible fingers are pushed beyond the outer edges of a flanged portion 342 of nozzle 292, thereby allowing the nozzle/filling assembly to be inserted further into vial adapter 282.

Inserting nozzle/filling assembly 280 into vial adapter 282 also causes a forward end of nozzle 292 to push against the distal end of inner valve

sleeve 286. Prior to contact with nozzle 292, inner valve sleeve 286 is biased axially away the vial-gripping portion of vial adapter 282 by resilient feet 344 provided on the proximal end of inner valve sleeve 286. In this initial position, an annular protruded area 346 on the inner diameter of inner valve sleeve 286 seals channels 330 formed in plug 288, thereby preventing liquid from passing out of central channel 326.

The insertion of nozzle/filling assembly 280 into vial adapter 282 pushes the inner valve sleeve 286 axially toward vial 290, compressing feet 344 and moving the sleeve so that the annular protruded area 346 does not seal channels 330 (Fig. 19). Piston 296 may then be drawn back to draw a dose of injectable liquid into fluid chamber 298 of nozzle 292. To create suction, the outer diameter of inner valve sleeve 286 may also be provided with an annular protruded area 348 to seal against the inner diameter of filling adapter 294.

After piston 296 has been withdrawn to draw in a dose of injectable fluid, filling adapter 294 may be broken away from nozzle 292. Typically, nozzle/filling assembly 280 is manufactured so that there is a frangible or breakable connection 360 between filling adapter 294 and nozzle 292 at the desired breaking point. Typically, after the filling adapter is broken away, it cannot be reattached to the nozzle by the user.

Referring now to Fig. 20, it will be appreciated that the described exemplary system prevents filling after the filling adapter has been broken away. Specifically, the figure depicts a non-compliant attempt to engage vial adapter 282 with nozzle 292 after the filling adapter has been broken away

from the front of nozzle 292 (e.g., after an injection has been delivered). As shown, flexible fingers 322 of vial adapter 282 are biased inward so as to block the flanged portion 342 of nozzle 292 surrounding injection orifice 300. Since filling adapter 294 (Figs. 18 and 19) has been broken away, no structure remains to spread the flexible adapter structure outward away from the blocking position to allow further axial movement of nozzle 292 toward vial adapter 282.

Because the flexible fingers act as a blocking mechanism or outer protective shroud that maintains nozzle 292 spaced apart from the end of inner valve sleeve 286, the respective fluid paths of vial adapter 282 and nozzle 292 are prevented from coming into contact, thereby guarding against contamination. Also, the nozzle is prevented from pushing against the end of inner valve sleeve 286, such that the nozzle cannot push the inner valve sleeve inward to disable the sealing of channels 330 by annular protruded area 346. Furthermore, because filling adapter 294 has been removed, a seal cannot be established to seal an enclosed area between the fluid paths. Accordingly, it should be appreciated that the removal of filling adapter 294 guards against contamination, prevents refilling and otherwise protects against unintended use.

As in the previous examples, the device depicted in Figs. 18-20 is configured to prevent delivery of an injection until the filling adapter is broken away and the refilling capability disabled. Specifically, the filling adapter may be disposed on the nozzle and sized so that the injection orifice is sufficiently

spaced from the injection site so as to prevent an effective injection from occurring.

Embodiment of Fig. 21

Fig. 21 depicts a further alternate embodiment of a vial adapter 380 and nozzle/filling assembly 382 Vial adapter 380 differs from the vial adapter of Figs. 18-20 in that it includes an alternate inner valve sleeve 384 which is biased into a sealed position by a spring 386. In the sealed position (not shown), the inner diameter of valve sleeve 384 seals channels 330 of plug 288. As in the example of Figs. 18-20, nozzle/filling assembly 382 includes a filling adapter 388 that spreads flexible fingers 322 apart to enable the components to be positioned axially close enough to one another to defeat the sealing of channels 330 and create suction to allow fluid to be drawn into fluid chamber 298 upon retraction of piston 296. During retraction of piston 296, the outer diameter of valve sleeve 384 seals against the inner diameter of filling adapter 388 to create suction.

Also, nozzle/filling assembly 382 differs from that of Figs. 18-20 in that frangible connection 390 is in a recessed location relative to injection orifice 300. Specifically, the frangible connection is spaced axially away in a rearward direction (e.g., rearward along the injection axis) from the generally planar area at the forward end of nozzle 392 that is placed onto the injection site during delivery of an injection. This may be desirable in certain applications, to ensure that sharp edges or other irregularities resulting from breakage are prevented from coming into contact with the injection site (e.g., a patient's skin). Also, as indicated, filling adapter 388 may be fabricated as a

separate piece, rather than integrally formed with nozzle 392. In the depicted example, the separate filling adapter piece may be ultrasonically welded to nozzle 392 or secured in place with any other desired method.

Embodiment of Figs. 22 and 23

Figs. 22 and 23 depict a further alternate embodiment of a vial adapter 400 and nozzle/filling assembly 402 according to the present disclosure. Similar to the example of Fig. 21, vial adapter includes a valve sleeve 404 which is biased (downward in Fig. 23) into a sealed position by a spring 406. A plug 408 is fitted into a cylindrical passage 410 of the vial adapter main body 412. As in the previous exemplary embodiments, plug 408 includes channels through which fluid can flow from vial 414 out through passage 410 and out of the vial adapter (e.g., into variable volume fluid chamber 416 in which plunger 418 is disposed). However, a lower end of sleeve 404 seals these channels until the sleeve is moved out of the sealing position (e.g., moved upward against the spring tension via engagement of the vial adapter with an appropriately shaped filling adapter).

Fig. 23 depicts engagement of nozzle/filling assembly 402 with vial adapter 400. As shown, filling adapter 420 may include on its inner diameter a circumferential ledge 422 sized to bear against a lower portion of valve sleeve 404 when the components are brought together. This urges valve sleeve 404 upward against the force of spring 406, as shown in the figure, such that fluid is now permitted to pass from passage 410, through the channels in plug 408, and into the injection device through injection orifice 424.

It will be appreciated that the nozzle/filling assembly 402 and vial adapter 400 provide similar advantages to the other embodiments discussed herein. In particular, filling adapter is configured so that it is frangibly connected to the nozzle, and must be broken away before an injection can be administered. As in the other embodiments, this breaking of the filling adapter prevents reuse by disabling the ability to refill the device. Specifically, once the filling adapter has been removed, the nozzle is no longer shaped to engage the opening of the vial adapter and actuate the adapter valve seal. Also, the vial adapter has an outer structure, as in previous embodiments, that acts as a protective shroud to protect the fluid pathway and reduce risk of contamination.

Embodiment of Figs. 24-27

Figs. 24-27 depict an embodiment 510 designed to be used with a prefilled cartridge 520. Injector 510 is virtually identical to injector 10 except that a ram extension 609 is included, and is mounted to ram 608 by a set screw 611. When mounted in place, set screw 611 is threaded into a threaded hole 617 in ram extension 609 so that the set screw extends into a notch 614 in ram 608. Plunger 630 is much shorter than plunger 130, and includes an O-ring 613. A cap 615 is also shown in Fig. 24, and cartridge 520 is slightly modified from cartridge 30 of injector 10. For example, cartridge 520 is typically fabricated of Topas® cyclic olyfin copolymer (COC) from Celanese/Ticona. This material has been found to be relatively inert and therefore normally will not react with typical formulations stored in the cartridge. Other parts that are the same as those previously described and

depicted in Figs 1-8 and 12 have been numbered by simply adding 500 to the numbers used in injector 10 shown in Figs 1-8 and 12. The description of the structure and operation of those parts will not be repeated.

The operation of injector 510 can be understood by making reference to Figs. 25-27. Fig. 25 shows injector 510 after prefilled cartridge 520 has been positioned in the injector but before firing. Ram extension 609 is shown to be mounted to ram 608 by set screw 611. Plunger 630 is positioned in the proximal end of prefilled cartridge 520, with cap 615 in place. In Fig. 25 main spring 602 is shown to be compressed using a winder (not shown), just like as in injector 10 that has been previously described.

In order to fire injector 510, trigger locks 576 are depressed, disengaging trigger lock legs 580 from notch 582 in main body 512. This permits the operator to slide trigger sleeve 514 forwardly on main body 512 as injector 510 is pressed against the patient. This releases main spring 602 as previously described, driving ram 608, ram extension 609 and plunger 630 forwardly or in a distal direction. This causes fluid to be ejected out orifice 642 and into the patient. This just - fired position of the components is shown in Fig. 26.

To prepare injector 510 for the next injection, the winder (not shown) compresses main spring 602 using the ratcheting operation previously described. Alternatively, the continuous rotation embodiment of the winder mechanism can be substituted. A dosage knob (not shown), like dosage knob 24 of injector 10, is turned, and this retracts ram 608 and ram extension 609 mounted to it. This facilitates the remove and replacement of cartridge 520

through the side of injector 510 as previously described in connection with injector 10. Because the distal end of ram extension 609 is normally perfectly positioned to abut the proximal end of plunger 630, injector 510 is now ready for the next injection (as shown in Fig. 25).

Embodiment of Figs. 28-32

The system depicted in Figs. 28-32 has been identified generally with the numeral 700. System 700 includes a vial 702, a vial adapter 704, a needle-free syringe/filling cap assembly 706, and needle-free syringe 708. Because system 700 includes components that are fairly different from those of the previously-described embodiments, the numerals for the component parts of system 700 do not correspond to the numerals used in the previously-described embodiments. It will be understood that once the needle-free syringe 708 of needle-free syringe/filling cap assembly 706 is broken away from the filling cap 710 of the needle-free syringe/filling assembly 706, the needle-free syringe may be used with any of the previously-described embodiments. It is the filling operation and the construction of the needle-free syringe/filling assembly 706 that is different in this system 700 from those embodiments described above.

As shown best in exploded Fig. 28, vial 702 of system 700 is of conventional design. Vial adapter 704 and filling cap 710 are new. Vial adapter 704 is of single-piece design, and includes a plurality of resilient fingers 716 that engage a lip 718 on vial 702. Vial adapter 704 further includes a cover 720 which includes a plurality of spaced vents 722, and an extension member 724. Extension member 724 has strengthening ribs 726

and a centrally disposed opening 728 designed to permit fluid to flow therethrough during the process in which the needle-free syringe draws fluid from the vial. Vial adapter 704 also includes a vial spike 738 extending downwardly into vial 702, designed to pierce a seal (not shown) on vial lip 718. Vial spike 738 includes a central channel that connects with opening 728 in extension member 724 so that fluid can pass from vial 702 and out vial adapter extension member 724. Vial adapter may take many other forms, and may include structure quite different from that set forth above and still be within the scope of the present disclosure.

A separate cap, not shown in exploded Fig. 28 but possibly identical to the filling cap 710 shown in Fig. 30, is used to cap extension member 724 of vial adapter 704 prior to use. Alternatively, the cap may be of any convention configuration.

Referring back to exploded Fig. 28, filling cap 710 is made up of essentially two parts. A distal portion 732 is mounted to the remainder of filling cap 710 by a frangible web 734, shown best in Figs. 31 and 32. Using a frangible web 734 to mount distal portion 732 to the remaining portion of filling cap 710 permits the filling cap to be broken away from its distal portion after needle-free syringe 708 is filled with fluid. The distal portion 732 thus remains in place in needle-free syringe 708 while the remaining portion of filling cap 710 is maintained in position over extension member 724 of vial adapter 704, providing a cover for vial 702.

Needle-free syringe 708 is shown in Fig. 28 to include a plunger 712 having an O-ring seal 714. Plunger 712 fits within the needle-free syringe to permit the system to draw fluid into and force fluid from the needle-free syringe. Plunger 712 typically includes a U-shaped end portion 736 such as that described in the prior embodiments. The U-shaped portion 736 may include a frangible member such as that depicted in Figs. 14-17 above. As described previously, this U-shaped end facilitates engagement of the plunger by the remainder of the injection assembly.

The operation of system 700 is best understood when reference is made to Figs. 29A - 29E. In order to fill needle-free syringe 708, vial 702 is filled with the fluid to be injected by first pushing vial adapter 704 onto vial lip 718. This causes spike 738 to pierce a seal (not shown), thereby opening a continuous fluid path between the vial and the needle-free syringe. This position of vial adapter 704 and vial 702 is shown in Fig. 29A.

Needle-free syringe/filling assembly 706 is designed to fit onto extension member 724 of vial adapter 704 as shown in Fig. 29B. The fit between extension member 724 and needle-free syringe/filling assembly 706 is a conventional luer fit so that it is tight, but may be assembled and disassembled without the use of tools.

Fig. 29C shows plunger 712 in needle-free syringe 708 in its withdrawn position. This is after fluid has been drawn into needle-free syringe 708 from vial 702 as described previously. Once needle-free syringe 708 has been filled, vial 702 with vial adapter 704 and filling cap 710 in place, is broken

away from needle-free syringe 708 as shown in Fig. 29D. As shown in detail in Fig. 31, the break takes place at frangible web 734 by merely tilting the two components with respect to each other. This provides a clean break so that the needle-free syringe is ready to be used to inject fluid into the patient as described in connection with the previously-discussed embodiments.

Once needle-free syringe 708 is filled with fluid to inject, an additional advantage of the depicted construction is that vial 702 and vial adaptor 704 are used as a "tool" to break away needle-free syringe 708 and distal portion 732 from filling cap 710. This results in the filling cap being maintained in place over vial adapter 704 after the needle-free syringe is broken away, as shown in Fig. 30. This reduces the likelihood of spillage or contamination of any other components or the surrounding area. As will be understood as this discussion continues, the breakage also prevents the needle-free syringe from being re-filled, thereby preventing its use for more than a single injection which could result in cross-contamination between different users and different injection fluids.

Reference should now be made to Figs. 31 and 32 where the details of depicted system 700 are more clearly shown. Fig. 31 shows distal end 732 of filling cap 710. It can be seen that distal portion 732 has an exterior surface that is designed to compliment the configuration of a well 740 in the end of needle-free syringe 708, adjacent injection orifice 742. This permits filling cap 710 to fit tightly into needle-free syringe 708 so that distal portion 732 is not dislodged during use or during the operation of breaking frangible web 734. This mounting is normally performed at the factory so that the health care

professional or other person administering the injection receives system 700 with filling cap securely mounted in place in the end of needle-free syringe 708.

In certain applications it may be desirable to spin-weld the distal portion 732 into the needle-free syringe. Spin-welding, as is known, causes one component to spin with respect to the other, with the tight fit and friction causing layers of plastic adjacent the surfaces to melt and then bond to each other. Alternatively, adhesive, such as UV-cured adhesive, may be used, or the parts may be ultrasonically welded. Any of these mounting methods securely mounts distal portion 732 to needle-free syringe 708 and results in a seal that prevents air or fluid from leaking between these two components.

Fig. 31 shows distal portion 732 being broken away from the rest of filling cap 710. However, prior to the distal portion being broken away, it should be understood that there is an axial gap between the end of nozzle 750 and the filling cap 710. Also included are four axially and radially-extending slots 752 which permit the fluid to flow between this axial gap and injection orifice 742. This is to permit injection fluid to flow from the vial, through the filling cap, through a pair of filling apertures 754, through the axial space and axially and radially-extending slots 752, through injection orifice 742, and finally into needle-free syringe 708. Filling apertures 754 are offset with respect to injection orifice 742 so that in the event the injector is accidentally fired while the filling cap is mounted to the needle-free syringe, the fluid will not be driven under high pressure back into the vial or into the patient's skin if an injection with the filling cap in place is attempted. Thus, it

can be seen that prior to the time filling cap 710 is broken away, a solid surface 755 will be facing injection orifice 742. The offset with respect to filling aperture 754 and injection orifice 742 will disrupt the flow enough to reduce any danger associated with such an accidental firing or intentional misuse of the product.

Distal portion 732 of filling cap 710 can be seen to be generally U-shaped in cross-section (see Fig. 31). The distally-facing end of distal portion 732 typically bottoms out in well 740, while a non-smooth surface is provided in the proximally-facing surface of the distal portion. In the depicted embodiment, a plurality of radially-extending ribs and slots create the non-smooth surface, although this non-smooth surface may be formed in any number of other ways. What is helpful about this feature is that a smooth-surfaced device cannot be fit over a nozzle 750 to create a sealed fit. This non-smooth surface is provided in the depicted embodiment in the form of ribs 744 (Figs. 31 and 32), and slots 746 (Fig. 32). Each of the slots 746 are shown in Fig. 32 to interconnect with an undercut circumferential portion 748. The term "undercut portion" may however refer to either slots 746 or circumferential portions 748.

The function of ribs 744 and slots 746 are to minimize the likelihood of anyone attempting to re-fill needle-free syringe 708 after the initial fill operation. When filling cap 710 is broken off from its distal portion 732, nozzle 750 is exposed, as well as the injection orifice 742 in the end of the nozzle. If someone attempts to fit most any structure over the end of needle-free syringe 708, the ribs and/or the slots will minimize the likelihood of a seal

being formed between such a filling device (not shown) and the end of needle-free syringe 708. Specifically, outwardly extending ribs 744 will prevent the formation of a seal caused by putting any flat surface over the end of the needle-free syringe, while slots 746 and undercut circumferential portions 748 will prevent the formation of a seal in the event someone is able to push a resilient member against the extending ribs to attempt to create a seal. If such a member is positioned over the slots, undercut circumferential portions 748 would permit air to be drawn in or fluid to be spilled out, and thereby prevent a seal. If something is fit over the circumferential portions, the position of the slots would permit air to be drawn in as well, thereby preventing formation of a seal. When a seal is prevented, a negative pressure cannot form as the plunger is withdrawn by the person attempting the re-filling operation. Therefore, fluid will not normally be drawn out of the vial and into the needle-free syringe without spillage. This should be enough to discourage re-use. A secondary advantage of this rib and slot configuration is to facilitate the molding of the device, which, given the intricate configuration of the various components, could otherwise be difficult.

Figs. 31 and 32 show that the nozzle 750 also includes a plurality of axially and radially extending slots 752. These are provided for the same purpose as the previously-discussed ribs and slots; that is, to help minimize the possibility of the formation of a seal by a member that is fit over the nozzle to attempt to refill the needle-free syringe. Specifically, if a tube is fit over the end of nozzle 750, air would normally be drawn in through the axially and radially extending slots 752. If a tube is simply pressed against the end of

nozzle 750, the radially extending portion of slots 752 will prevent the formation of a seal. Moreover, the broken-off, remaining portion of frangible web 734 may also assist in preventing formation of a seal in the event a tube is placed over nozzle 750. As noted above, an additional function provided by axially and radially-extending slots 752 is to facilitate the flow of injection fluid through apertures 754 and then into needle-free syringe 708 via injection orifice 742.

While these measures to prevent re-filling may seem to be extensive, they are sometimes critical in the use of injection systems. It is helpful to minimize the likelihood of reuse in order to prevent cross-contamination between patients and different injection fluids being used. This is often more important than simple hygiene because it must be remembered that oftentimes patients using this system already have some sort of health problem, which may well be infectious and communicable. If healthcare providers are to "first, do no harm", it is imperative that disease not be spread among users of an injection system. Also, most often this type of injection system will be used in developing countries, where due to limited resources users may be more inclined not to follow the safety principle of disposing the needle-free syringe after a single use, and therefore be more motivated to defeat the needle-free syringe's disabling feature.

Embodiment of Figs. 33-35

Figs. 33-35 depict another system 800 that can be used for intradermal injections. System 800 may be used with the filling system of system 700 or it

may be used with any conventional system for conveying injection fluid from a vial into a needle-free syringe. System 800 includes a needle-free syringe 808 and a forwardly-extending nozzle 850 with an injection orifice 842. It also includes a plunger 812 with an O-ring 814 positioned thereon. Plunger 812 includes a U-shaped end 836 as described in the prior embodiments.

The principle difference between embodiment 800 and those previously described is that a forwardly extending finger 860 is provided which prevents nozzle 850 and its injection orifice 842 from being pressed against the skin of the user, without an intradermal spacer being fit into place. Intradermal spacer 862 is provided to precisely position injection orifice 842 with respect to the skin of the user. Intradermal spacer 862 has a slot 864 which compliments the configuration of finger 860 and which permits the intradermal spacer to snap into place against needle-free syringe 808.

While various embodiments and arrangements of a needle-free injection system and method have been shown and described above, it will be appreciated that numerous other embodiments, arrangements, and modifications are possible and are within the scope of the invention. The foregoing description should be understood to include all novel and non-obvious combinations of elements described herein, and claims may be presented in this or a later application to any novel and non-obvious combination of these elements. The foregoing embodiments are illustrative, and no single feature or element is essential to all possible combinations that may be claimed in this or a later application.

I hereby claim:

1. A filling cap for use in a needle-free injection system comprising a vial-engagement portion and a needle-free syringe-engagement portion, with a frangible portion extending therebetween, the vial-engagement portion designed to removably engage a vial of fluid to be transferred into a needle-free syringe, the needle-free syringe-engagement portion designed to nonremovably engage an needle-free syringe.

2. The filling cap of claim 1, further comprising means for preventing the needle-free syringe from being filled more than once.

3. The filling cap of claim 1, further comprising a plurality of extensions or depressions facing outwardly from the needle-free syringe that prevent the needle-free syringe from being used more than once.

4. The filling cap of claim 1 wherein the needle-free syringe-engagement portion includes a non-smooth surface facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

5. The filling cap of claim 1 wherein the needle-free syringe-engagement portion includes at least one raised member facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

6. The filling cap of claim 5, further comprising a plurality of raised members facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

7. The filling cap of claim 1 wherein the needle-free syringe-engagement portion includes at least one undercut portion facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

8. The filling cap of claim 7 in which the undercut portion is a slot.

9. The filling cap of claim 7, further comprising at least one raised member facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

10. The filling cap of claim 1 wherein the vial-engagement portion includes a recess designed to compliment the configuration of a vial adaptor having an outwardly extending member, such that the recess receives the outwardly extending member.

11. The filling cap of claim 1 wherein the needle-free syringe-engagement portion includes a centrally-disposed solid portion facing the needle-free syringe.

12. The filling cap of claim 1 wherein the needle-free syringe-engagement portion includes at least one outwardly-facing, off-center aperture.

13. A method for filling a needle-free injector with injection fluid comprising the following steps, but not necessarily in the order recited:

selecting a needle-free syringe having an injection orifice at one end;

selecting a vial with injection fluid therein;

mounting one end of a vial adaptor to the vial such that a second end of the vial adapter faces away from the vial;

selecting a filling cap with one end complementing the configuration of the one end of the needle-free syringe and the other end complimenting the configuration of the second end of the vial adaptor, and having a frangible portion disposed between the two ends;

nonremovably fixing the one end of the filling cap to the one end of the needle-free syringe;

mounting the other end of the filling cap to the second end of the vial adaptor;

transferring injection fluid from the vial to the needle-free syringe; and

breaking the frangible portion of the filling cap without removing the one end from the needle-free syringe.

14. The method of claim 13 wherein the step of breaking the frangible portion of the filling cap is performed without removing the other end of the filling cap from the vial adaptor.

15. The method of claim 13, further comprising the step of selecting a one-piece vial adaptor.

16. A needle-free syringe for use in a needle-free injection system comprising:

a needle-free syringe body that is open on one end and includes an injection orifice at a second end;

a plunger disposed in the open end of the needle-free syringe body for drawing injection fluid into and driving injection fluid out of the needle-free syringe body via the injection orifice; and

a filling cap frangibly mounted to the second end of the needle-free syringe body and having an outwardly-extending recess for receiving an outwardly-extending portion of a vial adapter mounted to an injection-fluid-containing vial.

17. The needle-free syringe of claim 16 wherein a non-smooth surface faces outwardly from the second end of the needle-free syringe body to minimize the likelihood of the needle-free syringe being used more than once.

18. The needle-free syringe of claim 16, further comprising at least one raised member facing outwardly from the second end of the needle-free syringe body to minimize the likelihood of the needle-free syringe being used more than once.

19. The needle-free syringe of claim 16, further comprising a plurality of raised members facing outwardly from the second end of the needle-free syringe body to minimize the likelihood of the needle-free syringe being used more than once.

20. The needle-free syringe of claim 16 wherein the needle-free syringe-engagement portion includes at least one undercut portion facing outwardly from the second end of the needle-free syringe body to minimize the likelihood of the needle-free syringe being used more than once.

21. The needle-free syringe of claim 20 in which the at least one undercut portion comprises a slot.

22. The needle-free syringe of claim 20, further comprising at least one raised member facing outwardly from the second end of the needle-free syringe body to minimize the likelihood of the needle-free syringe being used more than once.

23. The needle-free syringe of claim 16, further comprising means for preventing the needle-free syringe from being refilled.

24. The needle-free syringe of claim 16, further comprising a plurality of raised or undercut portions at the second end of the needle-free syringe.

25. The needle-free syringe of claim 16 wherein the outwardly-extending recess receives the outwardly-extending portion of a vial adaptor in a luer fitting.

26. The needle-free syringe of claim 16 wherein the filling cap is mounted to the needle-free syringe in a luer filling.

27. The needle-free syringe of claim 16 wherein the filling cap includes at least one aperture facing the needle-free syringe which is offset with respect to the injection orifice.

28. The needle-free syringe of claim 16 wherein the filling cap includes a solid surface that faces the injection orifice.

29. A needle-free injection system comprising:

an injector body;

a trigger system disposed on the body for firing the injector;

a needle-free syringe to be positioned within the body, the needle-free syringe including an open end having a plunger positioned for drawing injection fluid into and driving injection fluid out of the needle-free syringe, and having a second end including an injection orifice;

a system for providing power to drive the plunger forward to drive injection fluid out of the injection orifice;

a filling system including a filling cap having one end that is frangibly mounted adjacent the second end of the needle-free syringe, radially outwardly of the injection orifice, the filling cap having another end defining a vial adapter mount for removably mounting the filling cap to a vial adapter that is positioned on a vial having injection fluid therein.

30. The filling cap of claim 29 wherein the second end of the needle-free syringe provides a non-smooth surface facing outwardly from the needle-free syringe to minimize the likelihood of the needle-free syringe being used more than once.

31. The injection system of claim 29 wherein at least one extension is disposed adjacent the second end of the needle-free syringe to minimize the likelihood of the needle-free syringe being re-filled after the frangibly mounted filling cap is broken away from the needle-free syringe.

32. The injection system of claim 29 wherein at least one depression is positioned adjacent the second end of the needle-free syringe to minimize the likelihood of the needle-free syringe being re-filled after the frangibly mounted filling cap is broken away from the needle-free syringe.

33. The injection system of claim 29, further comprising at least one extension disposed adjacent the second end of the needle-free syringe to minimize the likelihood of the needle-free syringe being re-filled after the frangibly mounted filling cap is broken away from the needle-free syringe.

34. The injection system of claim 29 wherein the filling cap is mounted adjacent the second end of the needle-free syringe in a luer fitting.

35. The injection system of claim 29 wherein the filling cap is removably mounted to the vial adapter in a luer fitting.

36. The injection system of claim 29, further comprising a one-piece vial adapter to be mounted to the vial.

37. The injection system of claim 29 wherein the one end of the filling cap includes a solid surface facing the injection orifice.

38. The injection system of claim 29, further comprising means for preventing re-use of the needle-free syringe.

39. The injection system of claim 29, further comprising a plurality of extensions and/or depressions defined in the second end of the needle-free syringe.

40. The filling cap of claim 1, wherein the vial-engagement portion includes a plurality of resilient fingers designed to engage the vial.

41. The filling cap of claim 1, wherein the vial-engagement portion includes a spike configured to pierce a covering on the vial and permit fluid to be drawn from the vial through the spike.

42. A device for filling a needle-free syringe, comprising: a vial-engagement portion and a needle-free syringe-engagement portion, with a frangible portion extending therebetween, the vial-engagement portion designed to engage a vial of fluid to be filled into the needle-free syringe, the needle-free syringe-engagement portion designed to nonremovably engage an needle-free syringe.

43. The device of claim 42, further comprising means for preventing the needle-free syringe from being filled more than once.

44. The device of claim 43, wherein the means for preventing the needle-free syringe from being filled more than once comprises a plurality of extensions or depressions facing outwardly from the needle-free syringe that prevent the needle-free syringe from being used more than once.

45. The device of claim 43, wherein the means for preventing the needle-free syringe from being filled more than once comprises a non-smooth surface in the needle-free syringe-engagement portion, facing outwardly from the needle-free syringe.

46. The device of claim 43, wherein the means for preventing the needle-free syringe from being filled more than once comprises at least one raised member in the needle-free syringe-engagement portion, facing outwardly from the needle-free syringe.

47. The device of claim 46, further comprising a plurality of raised members facing outwardly from the needle-free syringe engagement portion.

48. The device of claim 43, wherein the means for preventing the needle-free syringe from being filled more than once comprises at least one undercut portion in the needle-free syringe engagement portion, facing outwardly from the needle-free syringe.

49. The device of claim 48, in which the undercut portion comprises at least one slot.

50. The device of claim 48, wherein the means for preventing the needle-free syringe from being filled more than once further comprises at least one raised member facing outwardly from the needle-free syringe.

51. The device of claim 42, further comprising means for preventing engagement of the device with the needle-free syringe after the frangible portion has been broken.

52. The device of claim 42, wherein the device is without a system for forming the device back into a single, fluid-tight unit after the frangible portion has been broken.

53. The device of claim 42, wherein the device is fabricated of rigid plastic material.

54. The device of claim 42, wherein the device is fabricated of a rigid material so that if the vial onto which the vial-engagement portion is mounted is tilted with respect to the needle-free syringe onto which the needle-free syringe-engagement portion is mounted, the device will break at the frangible portion.

55. A method for filling a needle-free syringe, comprising:

selecting a needle-free syringe having an injection orifice and a fluid chamber with a plunger therein;

providing a device having a fluid channel, a vial-engagement portion and a needle-free syringe-engagement portion, with a frangible portion extending between the vial-engagement and needle-free syringe-engagement portions;

engaging the device with a vial having fluid therein to be passed into the syringe;

non-removably engaging the device with the syringe;

retracting the plunger to draw fluid into the syringe; and

breaking the device at the frangible portion while retaining the vial-engagement portion on the vial.

56. The method of claim 55, wherein the step of retracting the plunger to draw fluid into the syringe causes fluid to pass from the vial, through the channel, through the orifice, and into the fluid chamber.

57. The method of claim 56, wherein the step of retracting the plunger causes fluid to pass from the vial, through the channel, through a plurality of spaced apertures disposed radially outwardly of the orifice, and then through the orifice and into the fluid chamber.

58. The method of claim 55, wherein the step of breaking the device at the frangible portion comprises breaking the device such that it cannot be re-attached into a fluid-tight connection.

59. The method of claim 55, wherein the step of providing a device comprises providing a rigid device, and wherein the step of breaking the device at the frangible portion comprises tilting the vial with respect to the syringe until the device breaks at the frangible portion.

60. A needle-free syringe structure comprising:

a syringe portion adjacent one end, the syringe portion including a fluid chamber for receiving injection fluid and holding it for injection, an injection orifice for permitting injection fluid to be injected therethrough from the fluid chamber during injection, and a plunger for drawing injection fluid into and forcing fluid out of the fluid chamber via the injection orifice;

a vial-engagement portion adjacent an opposite end of the syringe structure for engaging the mouth of a vial containing injection fluid; and

a frangible connection between the syringe portion and the vial-engagement portion, the frangible connection being adapted to be broken after the chamber has been filled with injection fluid to prepare the syringe structure for injection.

61. The syringe structure of claim 60, wherein the frangible connection comprises a rigid plastic structure disposed radially outward of the orifice.

62. The syringe structure of claim 60, wherein the frangible connection further comprises structure that prevents a fluid-tight seal to be formed at the frangible connection after the connection has been broken.

63. The syringe structure of claim 60, wherein the syringe structure is rigid so that the frangible connection breaks when the vial-engagement portion is tilted with respect to the syringe portion.

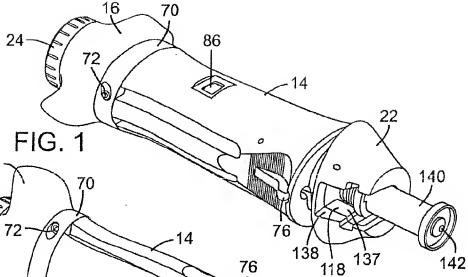

FIG. 1

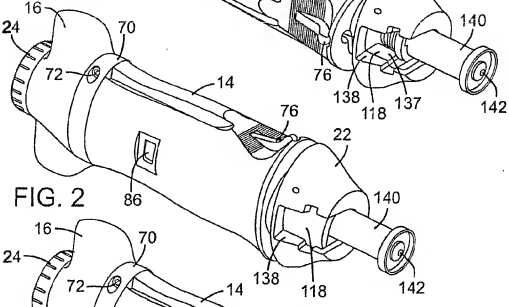

FIG. 2

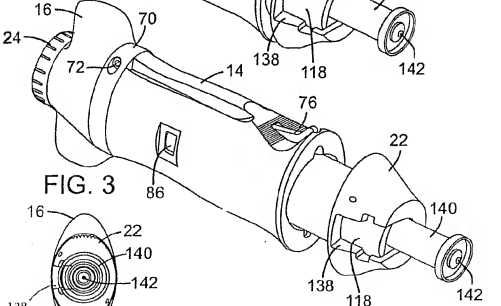

FIG. 3

FIG. 4

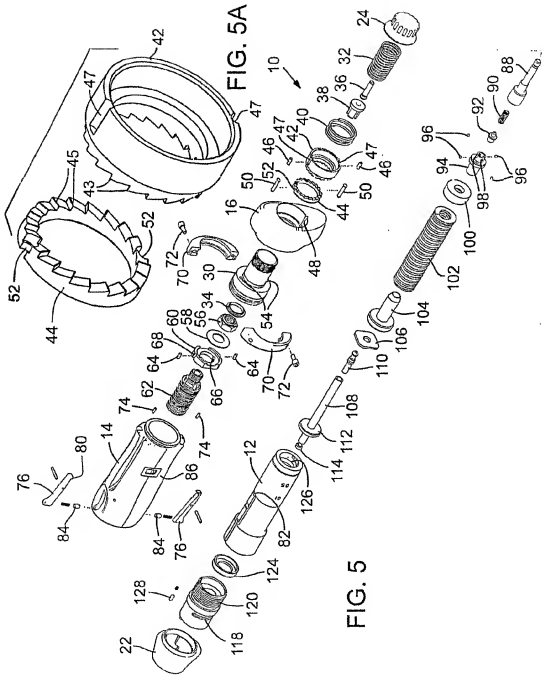
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FIG. 5A

FIG. 5

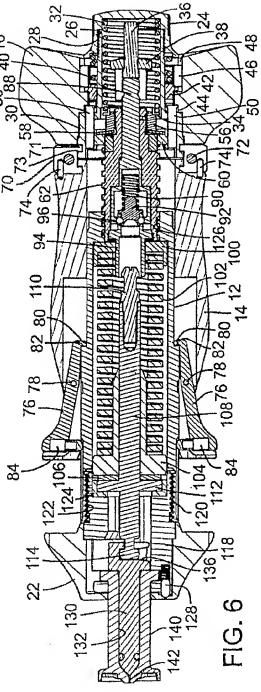

FIG. 6

FIG. 7

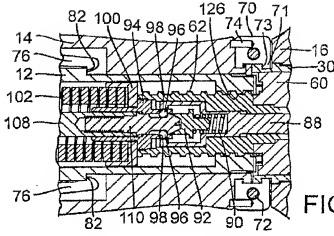

FIG. 6A

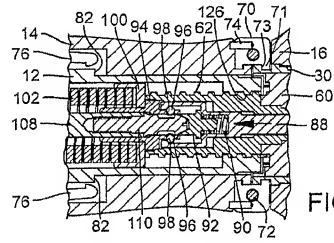

FIG. 6B

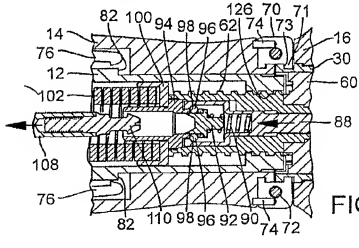

FIG. 6C

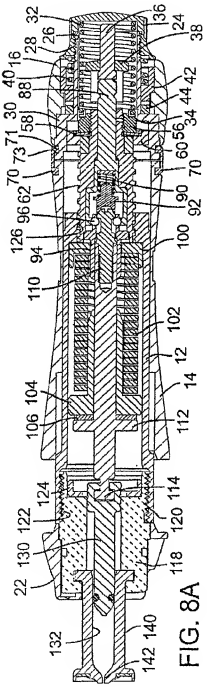
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FIG. 8A

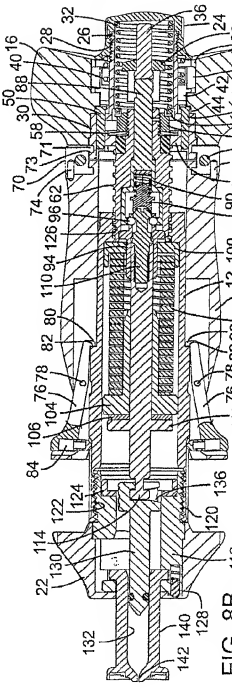
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FIG. 8B

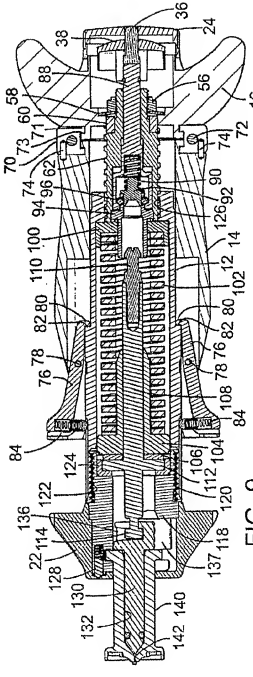

FIG. 9

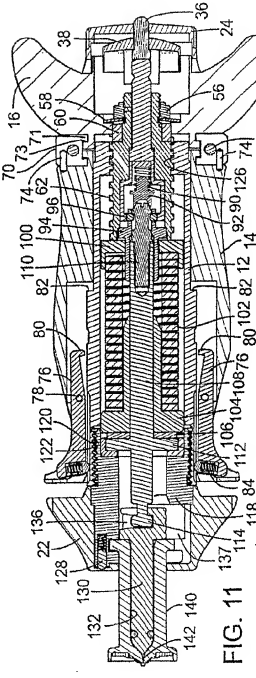

FIG. 11

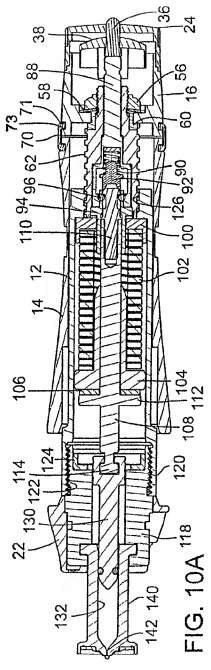

FIG. 10A

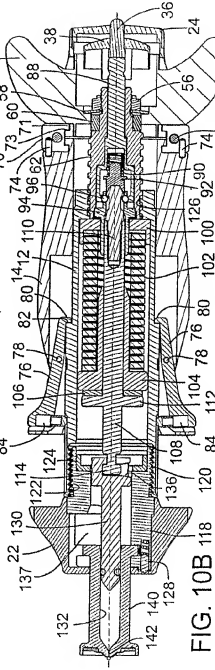

FIG. 10B

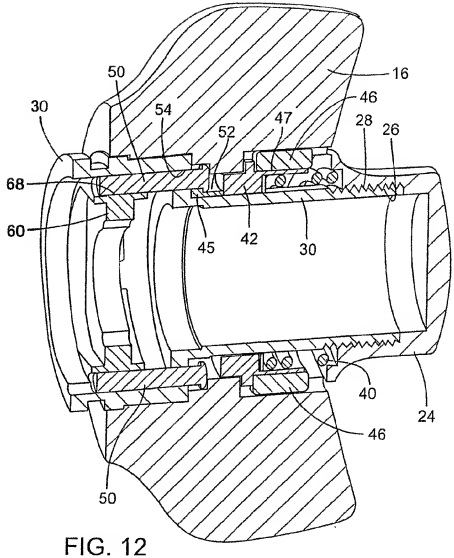

FIG. 12

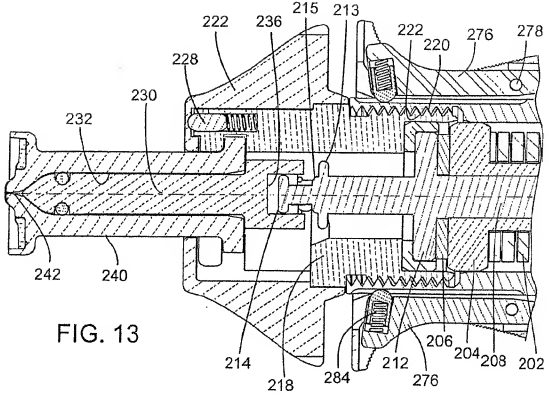
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FIG. 13

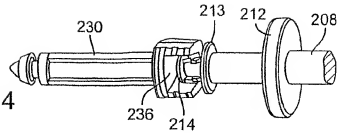

FIG. 14

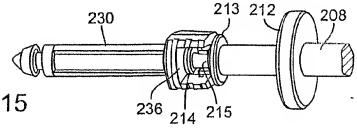

FIG. 15

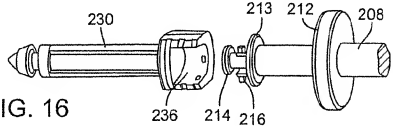

FIG. 16

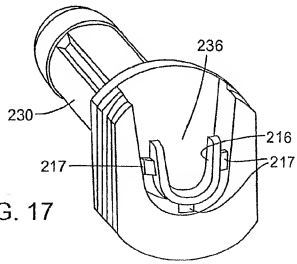

FIG. 17

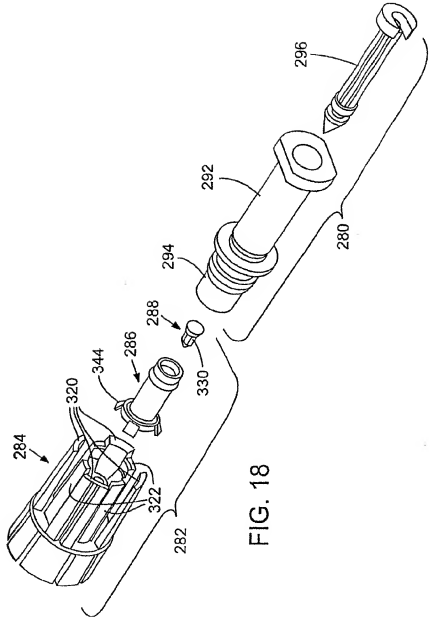

FIG. 18

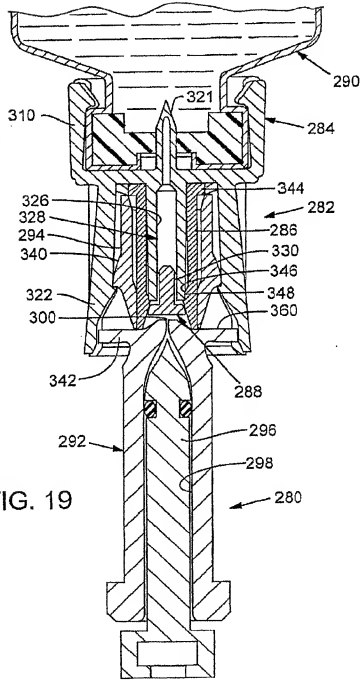
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FIG. 19

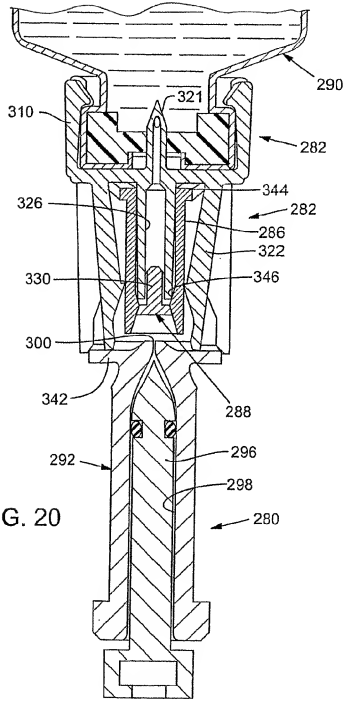
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FIG. 20

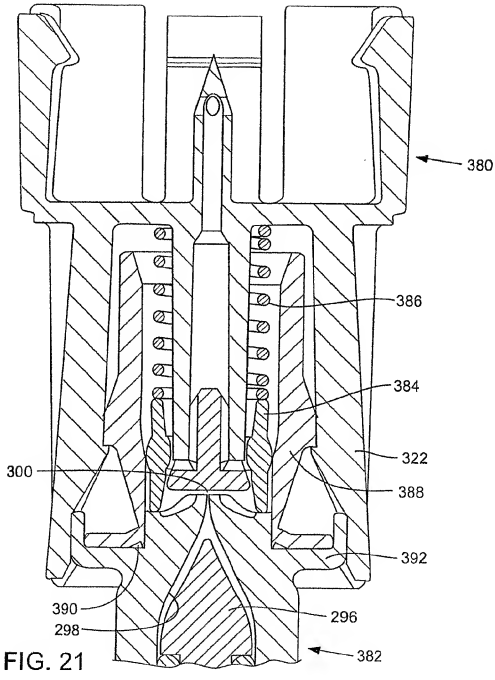

FIG. 21

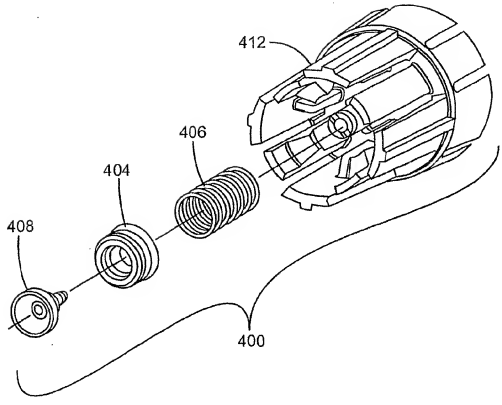

FIG. 22

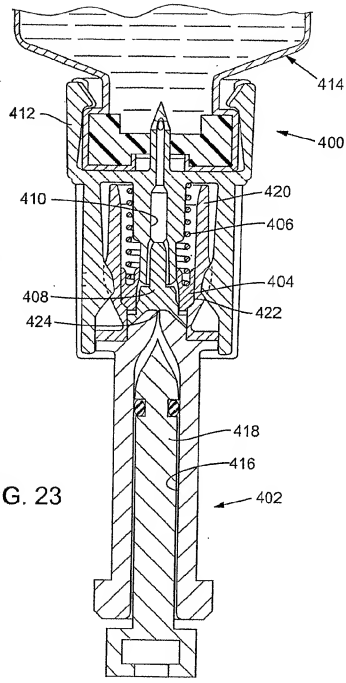

FIG. 23

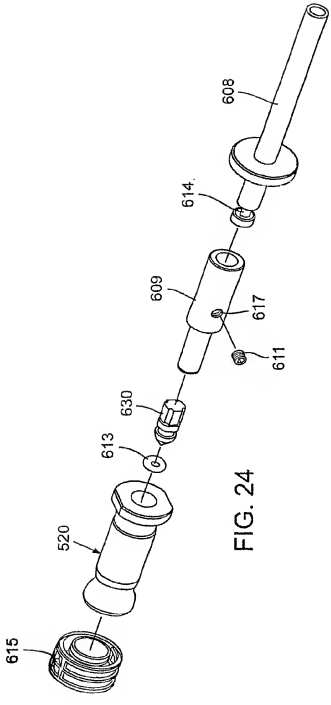

FIG. 24

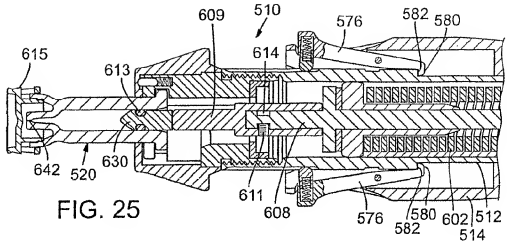

FIG. 25

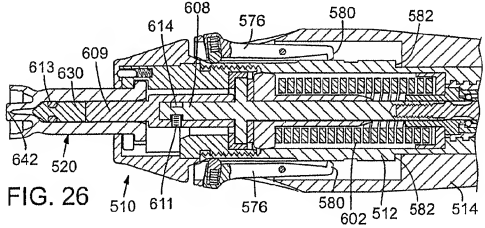

FIG. 26

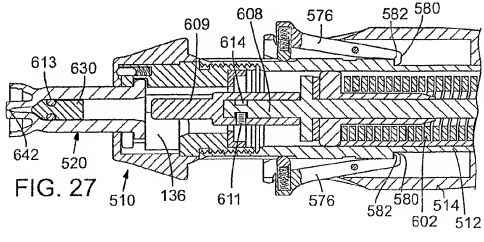

FIG. 27

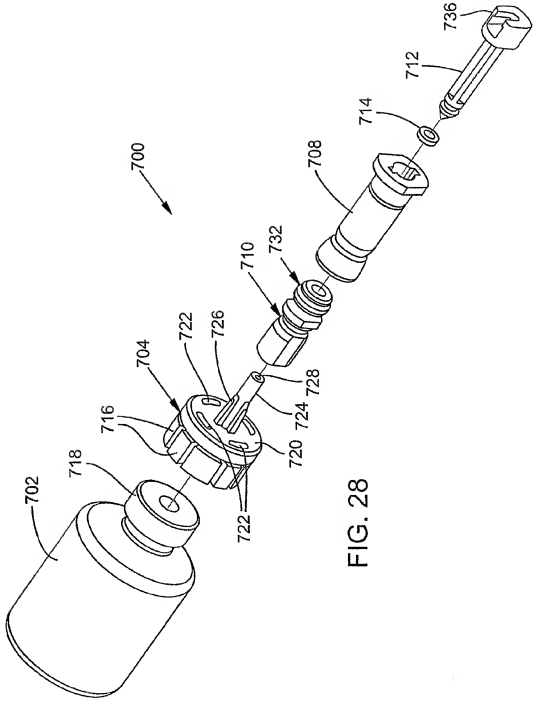
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FIG. 28

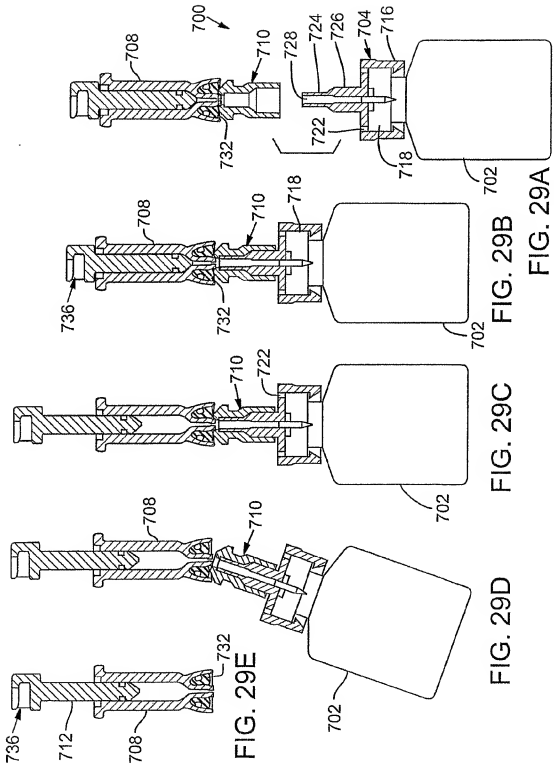
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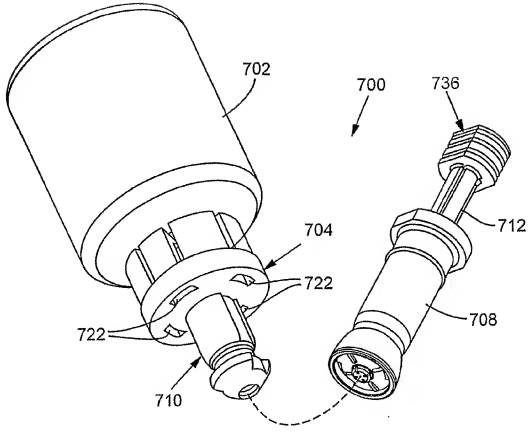
FIG. 29A



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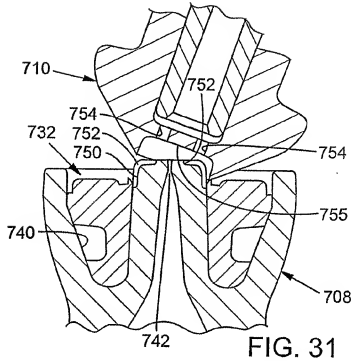
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FIG. 31

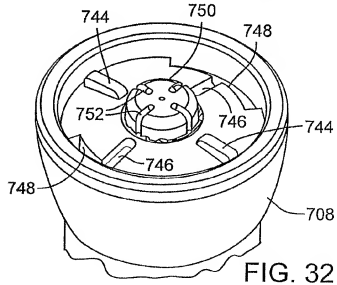
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FIG. 32

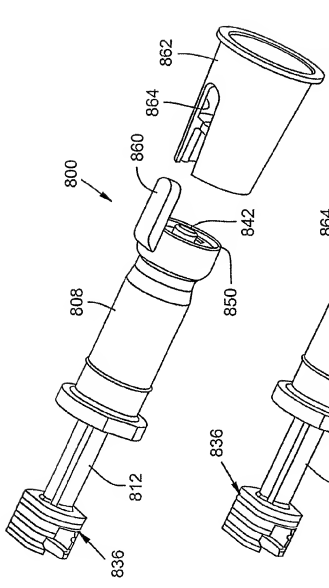

FIG. 33

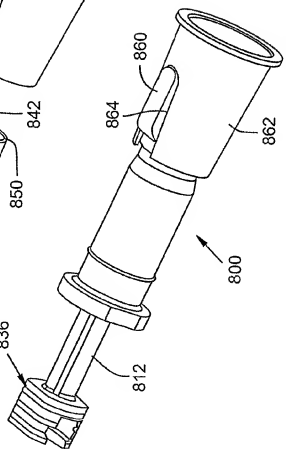

FIG. 34

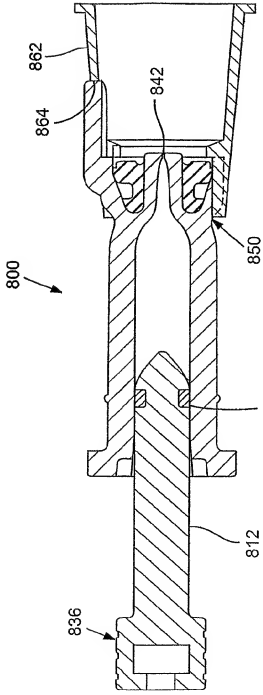

FIG. 35

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/39179

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/30 (2006.01)
USPC - 604/68, 110
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 5/30, 5/303, 5/307, 5/00 (2006.01)
USPC - 604/68, 69, 70, 71, 72, 110; 141/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPAT, IP.com, DialogPRO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,782,802 A (LANDAU) 21 July 1998 (21.07.1998), see entire document	1-10, 42, 43, 51-54
--		
Y		13-26, 29-30, 34-36, 38, 39-41, 55-56, 58-60, 62, 63
Y	US 5,599,302 A (LILLEY et al) 04 February 1997 (04.02.1997), see entire document	13-26, 29-30, 34-36, 38, 39-41, 55-56, 58-60, 62, 63
Y	US 5,569,189 A (PARSONS) 29 October 1996 (29.10.1996), see entire document	25-26, 34-35
A	US 5,334,144 A (ALCHAS et al) 02 August 1994 (02.08.1994), see entire document	1-63
A	US 5,256,142 A (COLAVECCHIO) 26 October 1993 (26.10.1993), see entire document	1-63
A	US 6,251,091 B1 (WESTON) 26 June 2001 (26.06.2001), see entire document	1-63
A	US 4,966,581 A (LANDAU) 30 October 1990 (30.10.1990), see entire document	1-63
A	US 6,755,220 B2 (CASTELLANO et al) 29 June 2004 (29.06.2004), see entire document	1-63
A	US 6,210,369 B1 (PATEL et al) 03 April 2001 (03.04.2001), see entire document	1-63

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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14 April 2006	22 JUN 2006
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